

REMARKS/ARGUMENTS

Prior to the present Amendment, claims 1 – 23 were pending. By the present Amendment, claims 1-20 and 22 are cancelled and claim 21 is amended. Claims 21 and 23 are now pending. Favorable reconsideration is respectfully requested in view of the following remarks.

REJECTION UNDER 35 U.S.C. § 102(b):

Claims 21 and 23 stand rejected as being anticipated by Unger et al. (5,244,460). In particular, the Examiner points to Col. 5, lines 22-33, of Unger et al. for allegedly teaching the concept of "a delivery instrument and a flowable agent causing the formation of lumens in the myocardium arranged to introduce particles at an entry site adjacent the cardiac tissue, generating a force external to the body to cause particles to pass through the contiguous tissue to target cardiac tissue without any mechanical means carrying said particles."

Independent claim 21, paragraph (a), as amended, includes the limitations of "providing a flowable agent comprising a plurality of *microspheres or microparticles having a particulate size range of approximately 1 micron to approximately 1mm* (emphasis added). Previously, the claim included limitations that the flowable agent comprised a plurality of "small particles." This is supported in the specification at page 53, lines 8-12, which states:

Before describing the exemplary embodiments of the microspheres shown in Figs. 15A-15I

The flowable materials may be of any particulate size from approximately 1 micron to approximately 1 mm. In Figs. 15A-15I, the particles are shown as being microspheres or microparticles.

The Examiner states that the delivery of peptides (as taught by Unger) constitutes a “flowable agent comprising a plurality of small particles.” The Examiner goes on to state that these are blood vessel growth promoting peptides, particularly ones which foster myocardial blood vessel growth (column 1, lines 9-10). The Examiner states that since peptides are delivered to the coronary artery (by an impetus of a particle moving force in the form of being injected from a catheter), but treat heart tissue, the peptide particles pass from the entry situs without any mechanical means carrying the particles into the target cardiac tissue.

The peptides of Unger are not microspheres or microparticles as claimed in claim 21. Peptides are a series of amino acids linked together by peptide bonds. Peptide chains longer than a few dozen amino acids are termed proteins. Peptides would properly be considered to be molecules.

Contrasted with a microsphere or microparticle, which can be of various shapes, as noted, for example, at page 29, lines 9-13:

Where the agents incorporate a solid component, the shape of the component can be varied from spheres to fibers to any other desired shape. A form of a microsphere may be utilized to treat the desired tissue region either by occupying space or by stimulating a biological response to the presence of them material or the release from the material of some chemical or biological element.

Biodegradable polymer microspheres are well known for drug delivery, and can be utilized for delivery of a molecular compound (e.g. peptides). For example, see page 56, lines

6 – 11:

Several embodiments of the subject invention utilize the incorporation of therapeutic agents into microparticles or microspheres that degrade over time and release the therapeutic agents. As a non limiting example, microparticles can be used to deliver any type of molecular compound, such as proteins, genetic materials, proteins, peptides....

This points to a characteristic difference between peptides and microspheres, where microspheres are capable of providing a structure to carry a peptide, but a peptide would not form a solid structure. Furthermore, by nature of having the size restriction of 1 micron to 1 mm in the claims, it also directs away from peptides, as molecular peptides would not fall reach the specified size range.

It is therefore asserted that claim 21 is in condition for allowance. It is respectfully requested that the Examiner pass claim 21 to allowance. Claim 23 depends from independent claim 21 and therefore should also be allowable.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance and claims 21 and 23 are allowable. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

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Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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